In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-0153V

STEPHANIE TOMPKINS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: June 28, 2024

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Zoe Wade, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On January 6, 2021, Stephanie Tompkins filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA"), a defined Table injury, after receiving a tetanus, diphtheria, acellular pertussis ("Tdap") vaccine on October 23, 2019. Petition at 1, ¶ 2. She further alleges that her "left shoulder injuries and sequelae lasted more than six months." *Id.* at ¶ 7.

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

The parties dispute whether the "severity requirement" (an element of all Program claims) is met. For the reasons discussed below, I find that Petitioner likely suffered the residual effects of her SIRVA for more than six months, and she has satisfied the other requirements of a compensable Table SIRVA injury. Petitioner is thus entitled to compensation under the Vaccine Act.

I. Relevant Procedural History

Along with the Petition, Ms. Tompkins filed some of the medical records required under the Vaccine Act. Exhibits 1-9; *see* Section 11(c). Over the subsequent ten-month period, she filed her remaining medical records, workers' compensation documents, and a signed statement.[3] Exhibits 10-13, ECF Nos. 6, 12, 18. After Petitioner provided her list of medical providers in April 2022 (ECF No. 21), the case was activated and assigned to the "Special Processing Unit" (OSM's adjudicatory system for resolution of cases deemed likely to settle). ECF No. 23.

In late 2022 and early 2023, Petitioner filed updated medical records and provided a demand and supporting documentation to Respondent. Exhibit 14, ECF No. 29; Status Report, ECF No. 30. On June 14, 2023, Respondent stated that he was willing to engage in settlement discussions. Status Report, ECF No. 32. Almost eight months later, the parties informed me they had reached an impasse. Status Report, ECF No. 40.

On March 29, 2024, Respondent filed his Rule 4(c) Report opposing compensation in this case. ECF No. 41. Emphasizing the six-month gap in treatment beginning in early February 2020 (four months post-vaccination), Respondent asserts that "the evidence does not preponderantly support that [P]etitioner's injury was ongoing during this period or that [P]etitioner's treatment in August 2020 was causally related to her pre-gap shoulder injury." *Id.* at 5. He maintains that "Petitioner has failed to satisfy the threshold six-month severity requirement under the Vaccine Act, and . . . is not entitled to compensation." *Id.* The matter is now ripe for adjudication.

II. Finding of Fact Regarding Duration

At issue is whether Petitioner continued to suffer the residual effects of the SIRVA for more than six months. Section 11(c)(1)(D)(i) (statutory six-month severity requirement).

[3] The statement was not notarized or signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 14.

A. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined.

Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

B. Analysis

I make the severity finding after a complete review of the record to include all medical records, affidavits or declarations, and additional evidence filed. Specifically, I base the findings on the following evidence:

- Prior to vaccination, Petitioner suffered from asthma, sinusitis, allergies, migraines, reoccurring lower back pain from an earlier injury, a goiter, and injury to her left-hand small finger in January 2019. Exhibits 4-7, 9.

- On October 23, 2019, Petitioner (then 44 years old and an operating room nurse) received the Tdap vaccine intramuscularly in her left deltoid at her hospital's emergency room ("ER"), after sustaining a puncture wound from a patient while at work. Exhibit 1 at 5; Exhibit 2 at 20, 27-28.

- On week later, on October 30, 2019, Petitioner visited the occupational health clinic, complaining of soreness followed by severe pain after receiving the Tdap vaccine. Exhibit 12 at 2, 4. She reported pain at a level of eight to nine out of ten. *Id.* at 4. Upon examination, Petitioner exhibited a reduced and pain range of motion ("ROM"), but no redness or swelling. *Id.* at 5. She was prohibited from lifting more than five pounds, instructed to

continue applying warm compresses, and prescribed Tylenol and a Medrol dosepak. *Id.*

- Returning to the occupational health clinic two days later, Petitioner continued to experience pain, estimated at a severity of seven, but had gained improvement in her ROM, attributed to the oral steroid medication prescribed on October 30th. Exhibit 12 at 16-17. She also exhibited redness and swelling which had started the previous day. *Id.*

- When seen again at the occupational health clinic three days later, on November 4, 2019, Petitioner's redness had resolved, but her pain and swelling continued. Exhibit 12 at 17. It was noted that she was likely suffering from cellulitis, in addition to her left shoulder pain. *Id.*

- By her next appointment on November 11, 2019, Petitioner had finished her oral steroid medication, but continued to experience pain and limited ROM. Exhibit 12 at 17. The treating physician opined that her injury was work-related and provided her with an orthopedic referral. *Id.* at 19, 21.

- Twelve days later, on November 23, 2019, Petitioner was seen by the orthopedist. Exhibit 12 at 24-25. Noting that her cellulitis had resolved, but that she continued to experience left shoulder pain and limited ROM, the orthopedist diagnosed Petitioner with rotator cuff tendonitis and ordered an MRI. *Id.*

- Performed on November 25, 2019, the MRI revealed findings indicative of infraspinatus tendinitis. Exhibit 2 at 10.

- At her initial physical therapy ("PT") evaluation on December 2, 2019, Petitioner complained of left shoulder pain that began with vaccination with pain levels ranging from one at best to seven at worst. Exhibit 3 at 231, 241-43. The therapist recommended that Petitioner attend PT twice weekly for four weeks. *Id.* at 234.

- When seen again by the orthopedist on December 9, 2019, Petitioner reported some early improvement with PT, adding that she was tolerating normal duties. Exhibit 12 at 26. The orthopedist administered a steroid injection. *Id.*

- Throughout 22 PT sessions in December 2019 through January 2020, Petitioner reported pain levels ranging from two to four with medication.

E.g., Exhibit 3 at 152, 144, 140, 135, 130, 125 (in chronologic order). At her 21st PT session on February 1, 2020, she estimated that her pain level was two out of ten with medication and seven out of ten when sleeping. *Id.* at 115.

- At her next orthopedic appointment on February 3, 2020, Petitioner reported that she "[c]ontinue[d] to make progress with physical therapy." Exhibit 12 at 32. The orthopedist concluded she "may continue her normal duties . . . [and] can be discharged from formal physical therapy." *Id.* He added that Petitioner should "continue with home exercise program" ("HEP"). *Id.*

- At her 22nd PT session on February 5, 2020, Petitioner reported pain at a level of three with medication (specifically Motrin). Exhibit 3 at 109. It was noted that she was being discharged from PT by her treating physician. *Id.*

- Nineteen days later, on February 24, 2020, Petitioner returned to the orthopedist, for follow-up of her left shoulder pain. Exhibit 12 at 34. Although she was "[t]olerating her normal job duties," Petitioner reported that she "[s]till ha[d] some discomfort [with] certain motions" and continued to perform her HEP. *Id.*

- Petitioner did not seek treatment for her left shoulder symptoms for six months thereafter. The only intervening record is from May 28, 2020, when she visited a dermatologist for treatment of a scaly papule in her nasal cavity. Exhibit 8 at 7. There is no mention of left shoulder pain in the record from this visit. *Id.* at 3-8.

- On August 27, 2020, Petitioner returned to the orthopedist, now reporting that "[s]he ha[d] been tolerating her normal job duties but [was] having increasing discomfort again in the left shoulder." Exhibit 12 at 68. Upon examination, the orthopedist observed "[s]ome mild loss of motion to internal rotation, [m]arkedly positive impingement sign, . . . [m]ild weakness to [the] rotator cuff, [and] [p]ainful arc of motion." *Id.* at 69. Characterizing her symptoms as a reoccurrence and causally related to her work-related injury, the orthopedist stated Petitioner would be scheduled for surgery. *Id.* at 69-70.

- On September 15, 2020, Petitioner underwent arthroscopic surgery, specifically left shoulder rotator cuff and labral debridement, subacromial bursectomy, and decompression, and acromioplasty.[4] Exhibit 12 at 54-58.

- Two days later, on September 17, 2020, Petitioner attended her first post-surgical visit with the orthopedist. Exhibit 12 at 39-40. X-rays confirmed a successful subacromial decompression. *Id.* at 39. The orthopedist instructed Petitioner to stop using her sling and begin PT as soon as possible. *Id.*

- The same day, Petitioner was evaluated by the physical therapist. Exhibit 3 at 90-106. In this record, her condition was described as "left shoulder pain following vaccine at ER in October 2019." Exhibit 3 at 91. Petitioner was described as obtaining "no significant relief" from twelve weeks of PT and undergoing arthroscopic surgery two days earlier. *Id.*

- Petitioner attended twelve more PT sessions in September and October 2020. Exhibit 3 at 8-89. At her last PT session on October 15th, she reported a pain level of six without medication. *Id.* at 8. She was instructed to follow-up with her treating physician for authorization of four additional weeks of PT. *Id.* at 11.

- On November 9, 2020, Petitioner was cleared to return to work full-time. Exhibit 12 at 74.

- Petitioner reported significant improvement at her final post-surgical appointment on December 17, 2020. Exhibit 12 at 41. Described as performing "her normal job duties," Petitioner continued to exhibit "some strength deficits . . . [and] discomfort on the endpoints of motion." *Id.* The orthopedist instructed Petitioner to discontinue formal PT and to continue her HEP and normal duties. *Id.*

- In her witness statement, signed without any date or notation related to penalty of perjury, Petitioner provided significant details regarding her initial injury and symptoms. Exhibit 13 at ¶¶ 3-8. Regarding her later symptoms, she stated only that she suffered the residual effects of her injury for more than six months. *Id.* at ¶ 10.

[4] Acromioplasty is the "surgical removal of an anterior spur of the acromion to relieve mechanical compression of the rotator cuff during movement of the glenohumeral joint." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ("DORLAND'S") at 20 (32th ed. 2012).

To satisfy the Vaccine Act's severity requirement in this case, Petitioner must show that she suffered symptoms of her alleged SIRVA beyond April 23, 2020 (assuming a same day onset which the record preponderantly supports). The above medical entries preponderantly suggest Petitioner suffered from pain and limited ROM from her vaccine and work-related injury through at least December 2020, and despite a six-month gap in treatment from February through August 2020.

When arguing that Petitioner has failed to meet this requirement, Respondent relies heavily upon the gap in treatment, arguing there is insufficient evidence to link her later symptoms to those she experienced during the initial four-month period from October 2019 through February 2020. Rule 4(c) Report at 5. However, the evidence in this case shows that the treatment gap coincided with the likely relief provided by the steroid injection Petitioner received in late December 2019, plus the PT she attended through February 2020. It is common for Vaccine Act petitioners to receive temporary relief for a modest duration from such conservative treatment. And the PT records showed Petitioner's symptoms had gradually improved, but not completely resolved, by her last PT session in February 2020. Exhibit 12 at 34. Furthermore, the gap in treatment coincided perfectly with the worldwide COVID Pandemic which monopolized medical resources at that time.[5] Although Petitioner sought treatment from her dermatologist in May 2020 (Exhibit 8 at 3-8), that one appointment is not sufficient to establish a lack of ongoing, albeit possibly mild and/or intermittent, left shoulder symptoms. And Petitioner's failure to mention any left shoulder symptoms during that visit is not problematic. It would be illogical for Petitioner to have made that complaint to her dermatologist.

Most telling in this case is the fact that all medical providers viewed Petitioner's symptoms as part of the same left shoulder condition. When Petitioner returned for treatment in August 2020, the orthopedist characterized her symptoms as a reoccurrence and causally related to her work-related injury. Exhibit 12 at 69-70. This description of left shoulder pain related to the Tdap vaccine received in October 2019, was then echoed throughout PT records from sessions in September and October 2020. *E.g.,* Exhibit 3 at 91.

The mildness and intermittent nature of symptoms Petitioner may have suffered during the first half of 2020 are highly relevant to damages, but do not prevent a favorable severity finding. Nor does the intermittent nature of Petitioner's symptoms prevent her from establishing sequela for more than six months. Accordingly, there is preponderant

[5] The WHO declared COVID-19 a Public Health Emergency of International Concern on January 30, 2020, and a pandemic on March 11, 2020. *See* https://www.who.int/europe/emergencies/situations/covid-19 (last visited on June 25, 2024).

evidence to establish Petitioner suffered the residual effects of her alleged SIRVA for more than six months.

III. Additional Requirements for Entitlement

A. Legal Standards

In addition to requirements concerning the vaccination received, the duration of petitioner's injury (discussed above in Section II), and the lack of other award or settlement,[6] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a Hep B vaccine. 42 C.F. R. § 100.3(a)(VIII)(B). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation ("QAI") are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

[6] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

B. Analysis

Respondent has stated no further objections to compensation, and I find Petitioner has otherwise satisfied all criteria for a Table SIRVA injury following receipt of the flu vaccine. There is no evidence of prior left shoulder pain, inflammation, or dysfunction or an alternative cause for Petitioner's symptoms. *See* 42 C.F.R. § 100.3(c)(10)(i), (iv) (first and fourth QAI criteria). And Petitioner experienced pain within 48 hours of vaccination and exhibited pain and limitations in ROM solely in her left, injured shoulder. *E.g.,* Exhibit 12 at 4 (first report of pain one-week post-vaccination); Exhibit 3 at 241 (pain onset identified on October 23, 2019, and linked to the Tdap vaccine); *see* 42 C.F.R. § 100.3(c)(10)(ii) & (iii) (second and third QAI criteria).

As I have determined in this ruling, the record supports a finding that Petitioner suffered the residual effects of his SIRVA for more than six months. *See* Section 11(c)(1)(D)(i) (the Vaccine Act's six-month severity requirement). Additionally, the vaccine record shows Petitioner received the Tdap vaccine at the ER in the medical facility in New Jersey where she worked after sustaining puncture wounds on her right forearm from a patient. Exhibit 1 at 5; Exhibit 2 at 20, 27-28; *see* Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i) (requiring administration within the United States or its territories). And there is no evidence that Petitioner has collected a civil award for his injury. *See* Section 11(c)(1)(E) (lack of prior civil award). Thus, Petitioner has satisfied all requirements for entitlement under the Vaccine Act.

IV. Appropriate Amount of Compensation

Although I have found Petitioner entitled to compensation, I expect the amount to be awarded for Petitioner's past pain and suffering to be on the lower end for a SIRVA case involving arthroscopic surgery. Although Petitioner reported severe pain initially (*e.g.* Exhibit 12 at 4), she obtained good, albeit temporary, relief prior to surgery (*e.g.*, *id.* at 34). And Petitioner's surgery included procedures required to address pre-existing conditions, which would have been unaffected or only slightly aggravated by vaccination. *Id.* at 54 (stating surgery included labral debridement and acromioplasty). Thus, Petitioner should not expect a substantial pain and suffering compensation (although this case did involve surgery).

Conclusion

Based on the entire record in this case, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA and the Vaccine Act's severity requirement needed for both Table and non-Table claims. Petitioner is entitled to compensation in this case.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master